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Dockets Management Branch HFA 305  
Food and Drug Administration  
5630 Fishers Lane  
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Rockville, MD 20857

October 15, 1999

Gentlemen:


The purpose of this letter is to comment on the proposed changes in regulations for treatment of opiate dependence with methadone and LAAM.

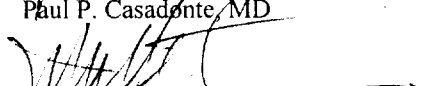
We have a number of years of clinical experience with LAAM, including participation in the VA Cooperative Study in 1973 and the LAAM Labeling Assessment Study in 1991. We have been regularly using LAAM at our Clinic since 1994 and have treated over 500 patients with this medication. We find it be a safe and effective treatment.

While LAAM is favored initially by patients who can come to the Clinic for three times a week dosing in the early phases of treatment, after they have stabilized and have become rehabilitated, they must continue to come for three times a week dosing. Individuals on methadone are eligible for once weekly pickup of medication. In addition, if a patient on LAAM must travel, it is necessary to transfer him to methadone, an option that our patients dislike. They report feeling drugged on methadone and do not like the sensation of returning to a somnolent state.

We have found that there is a sub-population of patients on LAAM who are free of illicit drug use for years, have jobs, stable living situations, and are responsible citizens. For these, take-out LAAM would be a reasonable option. Take-home LAAM should be available to these individuals. Diversion of LAAM is no more likely than methadone diversion.

Thank you.

  
Paul P. Casadonte, MD

  
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